§170.315(b)(1) Transitions of care

2015 Edition Cures Update CCG

Version 1.0 Updated on 06-15-2020

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	06-15-2020

Regulation Text

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§ 170.315 (b)(1) *Transition of care—*

(i) *Send and receive via edge protocol—*

(A) Send transition of care/referral summaries through a method that conforms to the standard specified in § 170.202(d) and that leads to such summaries being processed by a service that has implemented the standard specified in § 170.202(a); and

(B) Receive transition of care/referral summaries through a method that conforms to the standard specified in § 170.202(d) from a service that has implemented the standard specified in § 170.202(a)(2).

(C) XDM processing. Receive and make available the contents of a XDM package formatted in accordance with the standard adopted in § 170.205(p)(1) when the technology is also being certified using an SMTP-based edge protocol.

(ii) *Validate and display —*

(A) Validate C-CDA conformance – system performance. Demonstrate the ability to detect valid and invalid transition of care/referral summaries received and formatted in accordance with the standards specified in § 170.205(a)(3), (4), and (5) for the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates. This includes the ability to:

(1) Parse each of the document types.

(2) Detect errors in corresponding “document-templates,” “section-templates,” and “entry-templates,” including invalid vocabulary standards and codes not specified

in the standards adopted in § 170.205(a)(3), (4), and (5).

(3) Identify valid document-templates and process the data elements required in the corresponding section-templates and entry-templates from the standards adopted in § 170.205(a)(3), (4), and (5).

(4) Correctly interpret empty sections and null combinations.

(5) Record errors encountered and allow a user through at least one of the following ways to:

(i) Be notified of the errors produced.

(ii) Review the errors produced.

(B) *Display*. Display in human readable format the data included in transition of care/referral summaries received and formatted according to the standards specified in § 170.205(a)(3), (4), and (5).

(C) *Display section views*. Allow for the individual display of each section (and the accompanying document header information) that is included in a transition of care/referral summary received and formatted in accordance with the standards adopted in § 170.205(a)(3), (4), and (5) in a manner that enables the user to:

(1) Directly display only the data within a particular section;

(2) Set a preference for the display order of specific sections; and

(3) Set the initial quantity of sections to be displayed.

(iii) *Create.* Enable a user to create a transition of care/referral summary formatted in accordance with the standard specified in § 170.205(a)(3), (4), and (5) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates that includes, at a minimum:

(A)

(1) The data classes expressed in the standard in § 170.213 and in accordance with § 170.205(a)(4), (a)(5), and paragraphs (b)(1)(iii)(A)(*3)(i) through (iii)* of this section, or

(2) The Common Clinical Data Set in accordance with §170.205(a)(4) and paragraph (b)(1)(iii)(A)(*3*)(*i*) through (*iv*) of this section for the period until May 2, 2022, and

(3) The following data classes:

(i) Assessment and plan of treatment. In accordance with the "Assessment and Plan Section (V2)" of the standard specified in § 170.205(a)(4); or in

accordance with the “Assessment Section (V2)” and “Plan of Treatment Section (V2)” of the standard specified in § 170.205(a)(4).

(ii) Goals. In accordance with the “Goals Section” of the standard specified in § 170.205(a)(4).

(iii) Health concerns. In accordance with the “Health Concerns Section” of the standard specified in § 170.205(a)(4).

(iv) Unique device identifier(s) for a patient's implantable device(s). In accordance with the “Product Instance” in the “Procedure Activity Procedure Section” of the standard specified in § 170.205(a)(4).

(B) Encounter diagnoses. Formatted according to at least one of the following standards:

(1) The standard specified in § 170.207(i).

(2) At a minimum, the version of the standard specified in § 170.207(a)(4).

(C) Cognitive status.

(D) Functional status.

(E) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information.

(F) Inpatient setting only. Discharge instructions.

(G) Patient matching data. First name, last name, previous name, middle name (including middle initial), suffix, date of birth, address, phone number, and sex. The following constraints apply:

(1) Date of birth constraint.

(i) The year, month and day of birth must be present for a date of birth. The technology must include a null value when the date of birth is unknown.

(ii) Optional. When the hour, minute, and second are associated with a date of birth the technology must demonstrate that the correct time zone offset is included.

(2) Phone number constraint. Represent phone number (home, business, cell) in accordance with the standards adopted in § 170.207(q)(1). All phone numbers must be included when multiple phone numbers are present.

(3) Sex constraint. Represent sex in accordance with the standard adopted in § 170.207(n)(1).

Standard(s) Referenced

Paragraphs (b)(1)(i)(A) and (B)

§ 170.202(a)(2) Direct Project: ONC Applicability Statement for Secure Health Transport, Version 1.2 August 2015

§ 170.202(d) ONC Implementation Guide for Direct Edge Protocols, Version 1.1, June 25, 2014

Paragraph (b)(1)(i)(C)

§ 170.205(p)(1) IHE IT Infrastructure Technical Framework Volume 2b (ITI TF- 2b)

Paragraph (b)(1)(ii)

§ 170.205(a)(3) Health Level 7 (HL7®) Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012

§ 170.205(a)(4) HL7® Implementation Guide for CDA Release 2 Consolidation CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1 C-CDA 2.1, August 2015, June 2019 (with Errata)

§ 170.205(a)(5) HL7® CDA R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5).

Paragraphs (b)(1)(iii)(A)-(F)

§ 170.213 United States Core Data for Interoperability (USCDI)

§ 170.205(a)(3) Health Level 7 (HL7®) Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012

§ 170.205(a)(4) HL7 Implementation Guide for CDA Release 2 Consolidation CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1 C-CDA 2.1 with Errata, August 2015, June 2019 (with Errata)

§ 170.205(a)(5) Health Level 7 (HL7®) CDA R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5).

§ 170.207(a)(4) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, September 2019 Release

§ 170.207(i) Encounter diagnoses: The code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions ICD-10-CM as maintained and distributed by HHS, for the following conditions:

(i) Diseases.

(ii) Injuries.

(iii) Impairments.

(iv) Other health problems and their manifestations.

(v) Causes of injury, disease, impairment, or other health problems.

Paragraph (b)(1)(iii)(G)

§ 170.205(a)(4) HL7® Implementation Guide for CDA Release 2 Consolidation CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1 C-CDA 2.1, August 2015, June 2019 (with Errata)

§ 170.205(a)(5) HL7® CDA R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5).

§ 170.207(n)(1) Birth sex must be coded in accordance with HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor attributed as follows:

(i) Male. M

(ii) Female. F

(iii) Unknown. nullFlavor UNK

§ 170.207(q)(1) International Telecommunication Union E.123: Notation for national and international telephone numbers, e-mail addresses and web addresses and International Telecommunication Union E.164: The international public telecommunication numbering plan

Additional Resources

§ 170.207(a)(3) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) International Release July 31, 2012 and US Extension to SNOMED CT® March 2012

Certification Companion Guide: Transitions of care

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* Final Rule (ONC Cures Act Final Rule). It extracts key portions of the rule's preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the ONC

Cures Act Final Rule, 2015 Edition final rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

Link to Final Rule Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
Revised	No	Included	Yes

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(b)(1). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(b) "paragraph (b)" criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (a) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be tested once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) "VDT" and (e)(2) "secure messaging", which are explicitly stated.

Table for Privacy and Security

- If choosing Approach 1:
  - Authentication, access control, and authorization (§ 170.315(d)(1))
  - Auditable events and tamper-resistance (§ 170.315(d)(2))
  - Audit reports (§ 170.315(d)(3))
  - Automatic access time-out (§ 170.315(d)(5))
  - Emergency access (§ 170.315(d)(6))
  - End-user device encryption (§ 170.315(d)(7))

- Integrity (§ 170.315(d)(8))
- Encrypt authentication credentials (§ 170.315(d)(12))
- Multi-factor authentication (MFA) (§ 170.315(d)(13))

- If choosing Approach 2:
  - For each applicable P&S certification criterion not certified for Approach 1, the health IT developer may certify using system documentation that is sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces for each applicable P&S certification criterion that enable the Health IT Module to access external services necessary to meet the requirements of the P&S certification criterion. Please see the ONC Cures Act Final Rule at 85 FR 25710 for additional clarification.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.

- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, when different QMS are used, each QMS needs to be separately identified for every capability to which it was applied.
- When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively the developer must state that no accessibility-centered design was used.
- C-CDA creation performance (§ 170.315(g)(6)) does not need to be explicitly tested with this criterion unless it is the only criterion within the scope of the requested certification that includes C-CDA creation capabilities. Note that the application of § 170.315(g)(6) depends on the C-CDA templates explicitly required by the C-CDA-referenced criterion or criteria included within the scope of the certificate sought. Please refer to the C-CDA creation performance Certification Companion Guide for more details.

Table for Design and Performance

- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))
- Consolidated CDA creation performance (§ 170.315(g)(6))

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- The scope of this criterion is limited to the Consolidated CDA (C-CDA) Continuity of Care Document (CCD), Referral Note, and (inpatient setting only) Discharge Summary document templates. [see also 80 FR 62633]
- In combination with the C-CDA R2.1 standard, developers certifying to the USCDI must follow the guidance and templates provided in HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R2 Companion Guide, Release 2, for implementation of the C-CDA Release 2.1 standard. For example, details on how to structure and exchange Clinical Notes are included in the C-CDA Companion Guide.
- In order to mitigate potential interoperability errors and inconsistent implementation of the HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1, ONC assesses, approves, and incorporates corrections (Errata) as part of required testing and certification to this criterion. [seeFrequently Asked Questions #51] Certified health IT adoption and compliance with the following corrections are necessary because they implement updates to vocabularies, update rules for cardinality and conformance statements, and promote proper exchange of C-CDA documents. There is a 90-day delay from the time the CCG has been updated with the ONC-approved corrections to when compliance with the corrections will be required to pass testing (i.e., ETT: Message Validators- Cures Update C-CDA R2.1 Validator). Similarly, there will be an 18-month delay before a finding of a correction's absence in certified health IT during surveillance would constitute a non-conformity under the Program.

Paragraphs (b)(1)(i)(A) and (B)

Technical outcome – The health IT can send and receive transition of care (ToC)/referral summaries using one of the four edge protocols in the ONC Implementation Guide for Direct Edge Protocols.

Clarifications:

- For the purpose of sending ToC/referral summaries, a Health IT Module must demonstrate compliance with either the IHE XDR protocol or SMTP protocol. [see also 80 FR 62680]

- For the purpose of receiving ToC/referral summaries, a Health IT Module must demonstrate compliance with one of the following standards: IHE XDR, SMTP, POP3 and IMAP4. [see also 80 FR 62680]
- Certification to this criterion requires the exchange to take place using either TLS/SASL or a "secure network". A "secure network" is generally recognized as one where all the nodes (endpoints) are known, uniquely identified, access controlled, with strong end-to-end encryption. For example, a virtual private network (VPN) or a network physically isolated from any other with specialized equipment using endpoint encryption.
- The protocols listed in the Implementation Guide, section 1.3.1 explicitly list conformance to RFC 3501. The RFC, when originally published, mandated using the TLS_RSA_WITH_RC4_128_MD5 cipher suite within the TLS 1.0 bundle. RFC 3501 has had subsequent updates making the listed cipher suite obsolete and rescinded within the TLS 1.0 bundle. Current industry practice is to implement cipher suites that are compliant with TLS 1.1 (shall), TLS 1.2 (should), and TLS 1.0 (may).

Paragraph (b)(1)(i)(C)

Technical outcome – If the Health IT Module is certified to an SMTP-based edge protocol, the health IT must be able to receive and make available the contents of an XDM package that was created in accordance with the IHE IT Infrastructure Technical Framework Volume 2b (ITI TF-2b).

Clarifications:

- POP3 and IMAP4 are "SMTP-based" edge protocols for the purposes of receiving ToC/referral summaries. Thus, use of either will require a Health IT Module to demonstrate the requirements specified by this specific capability in the certification criterion. [see also 80 FR 62635]
- Health IT Modules should adhere to metadata requirements from the IHE Data Access Framework Document Metadata Based Access IG as included in the ONC XDR and XDM for Direct Messaging Specification. [see also 80 FR 62635]
- Health IT Modules are expected to support all commonly used Multi-Purpose Internet Mail Extension (MIME) types when receiving C-CDA and XDM packages. These MIME types will be specified in the test procedure. [see also 80 FR 62635]

Paragraph (b)(1)(ii)(A)

Technical outcome – The health IT can detect valid and invalid ToC/referral summaries upon receipt of C-CDA documents formatted to C-CDA Release 1.1 and 2.1.

Clarifications:

- We are requiring Health IT Modules to be able to receive and validate C-CDAs formatted to both C-CDA Release 1.1 and 2.1. While Release 2.1 largely ensures compatibility between C-CDA Release 1.1 and 2.0, it does not guarantee compatibility without further development effort. [see also 80 FR 62634]
- Developers have the discretion to exercise C-CDA validation in production, but certification will only require that the health IT be able to detect valid and invalid ToC/referral summaries during testing. We strongly recommend developers consider how the health IT will handle validation failures in production during the development of the technology, but it is not required for certification.
- Testing for the receipt of C-CDA Release 1.1 documents will offer two options – to test either a non-specified C-CDA document or a CCD. Note that Health IT Modules will be tested for receipt of all three document templates (i.e., CCD, Referral Note, and (inpatient setting only) Discharge Summary) for C-CDA Release 2.1.
- Error notification should be made available to authorized users of the receiving organization who can deal with the errors as appropriate and the error may be resolved by a support analyst or end user. [see also 80 FR 62634]
- There is no requirement that users be interrupted to be notified of errors, only that the user can access and review the errors. [see also 80 FR 62634]
- Receiving systems are not expected to translate codes from a source that has not formatted the data according to the applicable vocabulary standard required by the C-CDA Releases 1.1 and 2.1. [see also 77 FR 54220] However, receiving systems would be expected to identify data not formatted according to the applicable vocabulary standard as an error.

Paragraph (b)(1)(ii)(B)

Technical outcome – The health IT can display, for both C-CDA Releases 1.1 and 2.1, a human-readable C-CDA to a user.

Clarifications:

- No additional clarifications available.

Paragraph (b)(1)(ii)(C)

Technical outcome – The health IT allows a user to choose to display only the data within a particular C-CDA section, set a preference for the section display order, and set the initial number of sections to be displayed. This applies to both C-CDA Releases 1.1 and 2.1.

Clarifications:

- The use of the C-CDA CDA XSL style sheet will not be sufficient to meet the requirements of this provision. [see also 80 FR 62634]

Paragraphs (b)(1)(iii)(A) – (F)

Technical outcome – The health IT can create a C-CDA (formatted to Release 2.1) that includes the USCDI, Encounter diagnoses according to either ICD-10-CM or SNOMED CT® codes, Cognitive status, and Functional status.

- Ambulatory setting only – The user is able to create a C-CDA Release 2.1 that also includes the reason for referral, and the referring or transitioning provider's name and office contact information.
- Inpatient setting only – The user is able to create a C-CDA Release 2.1 Discharge Summary Document that also includes the discharge instructions.

Clarifications:

- In order to facilitate the translation of SNOMED CT® codes to ICD-10-CM in administrative systems, developers are encouraged to reference the publicly available mapping that the National Library of Medicine provides. [see also 77 FR 54220]
- We provide the following OIDs to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards:
  - ICD-10 Procedure Coding System OID: 2.16.840.1.113883.6.4
  - SNOMED CT® OID: 2.16.840.1.113883.6.96 [see also 80 FR 62612]
- Health IT Modules can present for certification to a more recent version of SNOMED CT®, U.S. Edition than specified by the USCDI per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62620]
- The C-CDA Cognitive Status Observation template has been deprecated in Release 2.1 and has been replaced with the Mental Status Observation template. Developers should use the Mental Status Observation template for cognitive status and be aware that the C-CDA

Validator will issue an error if the deprecated Cognitive Status Observation template is used instead.

Paragraph (b)(1)(iii)(G)

Technical outcome – The health IT can create a C-CDA (formatted to Release 2.1) that includes certain data to assist with patient matching. Unless otherwise specified, the developer should follow the guidance in C-CDA Release 2.1 for formatting the data.

Clarifications:

- These requirements concern only the ability to create a ToC/referral summary document that contains the data elements in accordance with the specified standards/constraints. The health IT is not required to demonstrate how it performs patient matching with these data for certification. [see also 80 FR 62637]
- C-CDA Release 2.1 allows suffix to be included as an additional qualifier to the last name field. [see also 80 FR 62636]
- We recommend receiving systems follow the guidance in CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 for normalizing last name before sending ToC/referral summary documents. [see also 80 FR 62636]
- “Previous name” is intended to capture situations where a patient may use an alias (e.g., maiden name, family name, legally changed last name). [see also 80 FR 62636]
- The C-CDA validation tool will test adherence to the use of the HL7 postal format for address. [see also 80 FR 62637]

Content last reviewed on June 18, 2020